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10/616,069	07/09/2003	William Payne Ross	26780-500	9951

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EXAMINER

ALEXANDER, JOHN D

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/616,069

Applicant(s)

ROSS ET AL.

Examiner

John D. Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 41, 42 and 45-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-40, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18, 41, 42 and 45-52 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to an apparatus with first and second multiplexers and a differential circuit, classified in class 600, subclass 509.
- II. Claims 19-40, 43, and 44, drawn to method and means for scanning, selecting, creating, and determining, classified in class 600, subclass 522.
- III. Claims 41 and 42, drawn to a plurality of electrodes, classified in class 600, subclass 372.
- IV. Claims 45-52, drawn to method and means for scanning a plurality of electrodes, classified in class 600, subclass 508.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because invention I does not require that the plurality of electrodes be spaced apart from one another a predetermined distance and positioned on columns. The subcombination has separate utility such as to pass a plurality of signals to a display for individual analysis without the need for intermediate multiplexers and differential circuitry.

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another process such as for receiving signals from a dedicated pair of electrodes rather than from a transient set selected from a larger plurality.

Inventions IV and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another process such as for receiving signals from a dedicated pair of electrodes rather than from a transient set selected from a larger plurality based on highest maximum value.

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another process such as for direct display of detected electrical activity without intermediate creation of a differential signal and determination of parameter data.

Inventions IV and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another

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materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another process such as for direct display of detected electrical activity without intermediate computations and waveform processing.

Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because invention II does not require the detailed scanning procedures recited in invention IV. The subcombination has separate utility such as the capture and processing of different waveform data such as EEG or EMG.

Because these inventions are distinct for the reasons given above and because the search required for Group I is not required for Groups II, III, or IV, the search required for Group II is not required for Groups III or IV, and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper.

During a telephone conversation with Brian Hopkins on February 8, 2005, a provisional election was made with traverse to prosecute the invention of Group II, Claims 19-40, 43, and 44. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-18, 41, 42, and 45-52 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claim 44** is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A computer program may not be claimed alone. To be statutory subject matter, the claim must be drawn to a tangible computer-readable medium that is encoded with a computer data structure or program.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 20-24, 27, 43, and 44** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 20 and 27 recite the limitation “the one or more ECG waveforms” in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim. Claim 19, from which Claims 20 and 27 depend, does not disclose more than one ECG waveform. Claim 24 recites the limitations “the interval” and “the... parameters” repeatedly throughout the claim. There is insufficient antecedent basis for these limitations in the claim. Claim 20, from which Claim 24 depends, does not disclose an interval or P, Q, R, S, and T parameters. Regarding Claims 43 and 44, it unclear whether Applicant seeks to claim particulars of computer instructions or method steps that are performed in cooperation with a computer. In case of the former, the steps should be changed to --computer readable instructions for scanning--, etc.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 19-22, 25, 29-31, 34-36, 38, and 43**, are rejected under 35 U.S.C. 102(b) as being anticipated by Cudahy et al. (Patent No. 5184620).

- Regarding **Claims 19, 20, 22, 25, 29, 34, 35, 38, and 43**, Cudahy et al. disclose scanning each of a plurality of spaced electrodes for a signal indicative of contact by an animal (Figs 1-3, elements 12; Fig. 5; Col. 6, lines 50-57); selecting a signal from each of at least a pair of electrodes, wherein each selected electrode includes a signal indicative of contact with the animal (Col. 6, lines 46-50 & 57-66; Col. 11, lines 25-28); creating a differential signal from the signals of the at least a pair of electrodes (Col. 1, lines 25-45; Col. 14, lines 2-6); and determining ECG waveforms and parameters such as P and Q waves (Col. 7, lines 29-34; Col. 9, lines 9-10). Regarding Claim 34, examiner recognizes that Applicant has invoked 35 U.S.C. 112 6<sup>th</sup> Paragraph and considers that Cudahy et al. disclose sufficiently equivalent means for achieving the claimed functions.
- Regarding **Claim 21**, Cudahy et al. detects variability by sensing the presence/absence of waveform parameters (Col. 7, lines 29-34).



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- Regarding **Claims 30 and 31**, examiner considers that Cudahy et al.'s signals indicative of good electrical contact will inherently have increased levels of electrical noise and interference, such as that from the body's electromechanical noise.
- Regarding **Claim 36**, Cudahy et al. disclose that the ECG monitor and analysis system includes a logic and control system (Fig. 1, element 46; Col. 6, lines 27-30).

***Claim Rejections - 35 USC § 102 / 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 19-31, 34-36, 38-40, and 43** are rejected under 35 U.S.C. 102(e) as anticipated by Hampton et al. (Patent No. 6445941) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hampton et al. in view of Ellenz (US Patent Application Publication 2001/0039385).

- Regarding **Claims 19, 25, 29, 34, 35, 38, 40, and 43**, Hampton et al. disclose scanning each of a plurality of spaced electrodes for a signal indicative of contact by an animal (Fig. 1, elements 100; Col. 6, lines 34-58; Col. 7, lines 6-21); selecting a signal from each of at least a pair of electrodes, wherein each selected electrode includes a signal indicative of contact with the animal (Col. 6, lines 59-67; Col. 7, lines 1-5); and determining heart rate and ECG waveforms and parameters (Fig. 7 & 8; Col. 6, lines 19-21). Regarding creation of a

differential signal from the electrode signals, it seems that the acquisition of an ECG, such as disclosed by Hampton et al., must inherently analyze the differences between selected electrode signals. Cudahy et al. provides a teaching that an ECG is, by nature, a representation of the “voltage differential appearing between two such electrodes or between one electrode and the average of a group of other electrodes” (Cudahy et al., Col. 1, lines 25-45). Alternatively, Ellenz discloses an ECG recorder and processor that includes a differential amplifier. It would have been obvious to one of ordinary skill in the art at the time of Applicant’s invention from the teaching by Ellenz to modify the ECG apparatus and method of Hampton et al. to include a differential amplifier. The motivation would have come from the teaching by Ellenz that such a differential step removes common mode noise from the collected electrode signals (§ 0032). Regarding Claim 34, examiner recognizes that Applicant has invoked 35 U.S.C. 112 6<sup>th</sup> Paragraph and considers that Hampton et al. disclose sufficiently equivalent means for achieving the claimed functions.

- Regarding **Claims 20-24, 26, and 27**, see Hampton et al.’s Figures 7 and 8.
- Regarding **Claims 28 and 39**, Hampton et al. further disclose amplifying the signals (Col. 2, line 49).
- Regarding **Claims 30 and 31**, examiner considers that Hampton et al.’s signals indicative of animal contact will inherently have increased levels of electrical noise and interference, such as that from the body’s electromechanical noise.
- Regarding **Claim 36**, Hampton et al. disclose the use of a conventional logic chip (Col. 7, line 14).

***Claim Rejections - 35 USC § 103***

**Claims 28, 32, 33, 39, and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cudahy et al. in view of Schiff (Patent No. 3614478). Cudahy et al. do not explicitly disclose that their ECG monitoring method and apparatus includes amplification and filtering of the electrode signals. However, Schiff provides a teaching that it is known to provide an ECG monitor with a differential amplifier and a 60Hz filter (Fig. 4, elements 150 & 152). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by Schiff to modify the ECG method and apparatus of Cudahy et al. to include a differential amplifier and 60Hz filter. The motivation would have come from Schiff's teachings that these features help detect minute patient signals and remove common power line interference from the examined signal (Col. 5, lines 50-62).

**Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cudahy et al. in view of Donehoo et al. (Patent No. 5788644). As related above, Cudahy et al. disclose an ECG monitoring system and method that selects the signals from particular electrodes based on optimal electrical contact with a patient. However, Cudahy et al. do not explicitly disclose that the means for scanning or selecting the electrode signals includes a multiplexer controlled by the processor. Donehoo et al. disclose an ECG monitor and analysis system that employs a multiplexer under processor control to select, from multiple electrodes, the signals to be used for further processing and analysis (Fig. 3, element 16; Col. 4, lines 12-56). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by Donehoo et al. to modify the ECG monitoring system and method of Cudahy et al. to include

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a multiplexer under processor control as the means select optimal electrode signals. The motivation would have been to provide an efficient, time-tested means for selection of the desired electrodes signals from amongst a larger plurality.

**Claims 32 and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton et al. in view of Schiff. Hampton et al. do not explicitly disclose that their small animal ECG method includes filtering of the electrode signals. However, Schiff provides a teaching that it is known to provide an ECG monitor with a 60Hz filter (Fig. 4, element 152). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by Schiff to modify the ECG method and apparatus of Hampton et al. to include a 60Hz filter. The motivation would have come from Schiff's teaching that such filtering removes common power line interference from the examined signal (Col. 5, lines 59-62).

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA



JEFFREY R. JASTRZAB  
PRIMARY EXAMINER  
2/13/06